IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8546

Bartle, C.J. September 18, 2010

Lonnie D. Gleave ("Mr. Gleave" or "claimant"), a class member under the Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In April, 2008, claimant submitted a completed supplemental Green Form to the Trust signed by his attesting physician, Chun Hwang, M.D.[3] Based on an echocardiogram dated July 26, 1999, Dr. Hwang attested in Part II of claimant's Green Form that he had moderate mitral regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50%-60%, and ventricular fibrillation or sustained ventricular

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2. (...continued)
describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. A claimant who has received Matrix Benefits may file a supplemental Green Form with the Trust in the event his or her medical conditions have worsened. See Settlement Agreement § IV.C.3.

tachycardia which results in hemodynamic compromise.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level V benefits[5] in the amount of $704,750.[6]

In September, 2008, the Trust forwarded the claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala concluded that there was no reasonable medical basis for Dr. Hwang's finding that claimant suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. Specifically, Dr. Penkala stated:

> The [c]laimant has had repeated episodes of documented non sustained [ventricular tachycardia]. On a Holter (11/3/04) the [non-sustained ventricular tachycardia] was said to correlate with patient feeling

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4. Dr. Hwang also attested that claimant had mild aortic regurgitation, a heart transplant, and New York Heart Association Functional Class II symptoms. These conditions, however, are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she otherwise qualifies for Level II, Level III, or Level IV benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d). As the Trust does not contest that claimant satisfied the criteria for Level II benefits, the only issue is whether claimant suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

6. In March, 2002, claimant was paid Matrix A-1, Level II benefits in the amount of $426,912. According to the Trust, if entitled to Matrix A-1, Level V benefits, claimant would be entitled to Matrix Benefits in the amount of $1,131,662. The amount at issue, therefore, is the difference between the Level II Matrix Benefits already paid and the amount of Level V Matrix Benefits.

> "mildly lightheaded." I did not find any documentation of [ventricular fibrillation]/sustained [ventricular tachycardia] resulting in hemodynamic compromise.

The Trust then issued a post-audit determination that claimant was not entitled to Matrix A-1, Level V benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In contest, claimant submitted a letter from his attesting physician, who stated, in relevant part, that:

> Mr. Gleave is a patient who was under my care and I have not seen him for several years and who has been apparently having some legal documentation requirement to state indication for ICD[8] implantation that he received on June 30, 2004 and for cardiomyopathy and ventricular tachycardia.
>
> The patient has undergone an electrophysiology study on June 29, 2004 and confirmed that the patient had an inducible ventricular

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Gleave's claim.

8. "ICD" is an acronym for an implantable cardioverter defibrillator, which is a device that monitors and, if necessary, corrects episodes of rapid heartbeat. If the heartbeat elevates above a normal rhythm (ventricular tachycardia), an ICD will stimulate the heart to restore a normal rhythm. If the heartbeat elevates to a potentially fatal rhythm (ventricular fibrillation), an ICD will produce an electric shock (defibrillation) to reset the heartbeat. ICDs are similar devices to pacemakers, which are used frequently to correct a heart rhythm that is too slow (bradycardia).

> tachycardia, nonsustained nature and underwent catheter ablation procedure of [ventricular tachycardia] focus, unfortunately it was not able to be eliminated completely.
>
> In that regard on the following day on June 30, 2004, the patient did receive ICD implantation for indication of dilated cardiomyopathy with ejection fraction of approximately 18% based on the echocardiogram and significant left ventricular dyssynchrony and ventricular tachycardia and the patient underwent a biventricular ICD implantation.
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> To dictate this letter medical records from the hospital at Utah Valley Regional Medical Center at that time and also the prior hospitalization on February 10, 2004 and subsequent hospitalization records were reviewed. There is a clear-cut documentation of numerous runs of ventricular tachycardia on 12-lead electrocardiogram also on Telemetry monitorization that clearly indicated need for biventricular ICD implantation for improvement of his heart failure and also primary prevention for sudden cardiac death syndrome.

According to claimant, he should receive Level V benefits because "[n]on-sustained [ventricular tachycardia] is every bit as dangerous as [s]ustained [ventricular tachycardia], especially when my ejection fraction was only 18%." (emphasis omitted). Claimant also argued that the medical conditions that warranted payment of his Level II claim also support his entitlement to Level V benefits.

The Trust then issued a final post-audit determination, again determining that claimant was not entitled to Matrix A-1, Level V benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process

established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Gleave's claim should be paid. On August 19, 2009, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8253 (Aug. 19, 2009).[9]

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response, as well as a supplemental response (consisting of a series of letters), upon the Special Master. The Trust did not submit a reply and instead relied on the record and pleadings submitted to date. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for his attesting physician's finding that he suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See id. Rule 24. Ultimately, if we determine that there is no

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9. Initially, claimant appealed to this court from the Trust's final post-audit determination and requested arbitration pursuant to the Settlement Agreement. By letter dated May 21, 2009, the Trust advised claimant that the Trust would treat claimant's letter and appeal as a request to proceed through the show cause process under the Settlement Agreement. By letter dated June 8, 2009, claimant acknowledged that his claim would be resolved pursuant to PTO No. 2807.

reasonable medical basis for the answer in claimant's Green Form that is at issue, we must confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Gleave again argues that he should receive Level V benefits because "[t]he non-sustained [v]entricular [t]achycardia, I was having was every [b]it as dangerous (especially with the damaged [m]itral [v]alve it had to work [w]ith), as the [s]ustained [ventricular tachycardia] would have been." (emphasis omitted).[10] In addition, claimant argues that he should prevail because his ingestion of Diet Drugs "damaged the [m]itral [v]alve in [claimant's] heart that started all of this."[11] (emphasis omitted).

After reviewing the entire Show Cause Record, we find that claimant has not established a reasonable medical basis for

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10. Claimant also asserted that the auditing cardiologist should have been advised of his heart transplant. The auditing cardiologist's certification, however, reflects that she reviewed all of claimant's medical records, which included records relating to claimant's heart transplant procedure. In any event, as claimant does not have the requisite medical conditions necessary to recover Level V benefits based on his heart transplant, this issue is not pertinent to the resolution of this claim. See Settlement Agreement § IV.B.2.c.(5)(b)iii).

11. Claimant also submitted several articles regarding ejection fraction, hemodynamic compromise and ventricular tachycardia.

his Level V claim for Matrix Benefits. Under the Settlement Agreement, a claimant is entitled to Level V benefits if:

> The individual otherwise qualifies for payment at Matrix Level II, III, or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

Settlement Agreement § IV.B.2.c.(5)(d). As claimant does not contend that he suffers from ventricular fibrillation, the only issue is whether claimant suffers from sustained ventricular tachycardia which results in hemodynamic compromise.

As to this issue, the auditing cardiologist concluded, and the letter submitted by claimant's attesting physician confirms, that claimant never suffered from sustained ventricular tachycardia as required by the Settlement Agreement for Level V benefits. Specifically, claimant's attesting physician stated that Mr. Gleave's ventricular tachycardia was of a "nonsustained nature." In a letter dated "April 23, 2009/May 1, 2009," claimant also conceded that his attesting physician (notwithstanding the Green Form answer) did not assert that claimant has ventricular fibrillation or sustained ventricular tachycardia:

> Neither Dr. Dahl [n]or Dr. Hwang, ever "asserted" that I had ventricular fibrillation or sustained ventricular tachycardia, as noted by Dr. Penkala, and it was not Dr. Hwang's intent to "ARGUE" with her about finding medical records showing that I had "Sustained Ventricular Tachycardia." I believe that it was his intent to show that there was a "REASONABLE MEDICAL BASIS" why he had to implant the ICD defibrillator for "improvement of my heart

> failure and also for primary prevention for cardiac death syndrome."[12]

(emphasis omitted.)

Moreover, claimant's medical records support the auditing cardiologist's determination that Mr. Gleave failed to provide any support for the Green Form answer that he suffered sustained ventricular tachycardia. For example, as reflected in a December 12, 2003 medical record from the Central Utah Cancer Center, which was prepared by claimant's attesting (and treating) physician:

> Mr. Gleave is returning today for followup evaluation. He underwent initial treatment with amiodarone for multiple recurrent nonsustained left ventricular tachycardia. Unfortunately, even amiodarone therapy is not able to successfully control the patient's clinical symptoms. For that regard, the patient apparently is also being evaluated by Dr. Dahl to undergo cardiac catheterization to evaluate for underlying ischemic heart disease.

Similarly, as stated in a June 30, 2004 "History and Physical Report" from the Utah Valley Regional Medical Center:

> SUMMARY:
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> This is a 65-year-old male patient who has well documented cardiomyopathy with recurrent

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12. Notwithstanding this earlier letter, in his response, claimant argues that this letter indicates that his ventricular tachycardia "must have been sustained" due to his attesting physician's decision that claimant should receive an ICD after all prior therapies had failed to prevent the recurrence of his ventricular tachycardia. (emphasis omitted). The plain text of the letter of claimant's attesting physician, however, contradicts claimant's interpretation as his attesting physician unequivocally states that claimant only had non-sustained ventricular tachycardia.

> nonsustained burst of salvos of ventricular tachycardia with significant symptoms of syncope and dizziness and has been referred for evaluation.

An October 30, 2004 "History/Physical Report" from the Utah Valley Regional Medical Center also states, in relevant part, the following:

> LABORATORY STUDIES:
> Rhythm strip does show intermittent nonsustained ventricular tachycardia with underlying [atrioventricular] paced rhythm.
>
> * * *
>
> ASSESSMENT:
> 1. Congestive heart failure in a patient with nonischemic cardiomyopathy with an ejection fraction of 18%.
>
> 2. Nonsustained ventricular tachycardia.
>
> 3. Diabetes.

In addition, a November 3, 2004 "Noninvasive Cardiology Procedure Report" prepared by Dr. Hwang states that:

> DIAGNOSIS:
> Ventricular tachycardia.
>
> PROCEDURE:
> The 24-hour Holter monitorization revealed that the patient has essentially 100% [atrioventricular] sequentially paced rhythm, with frequent [premature ventricular complexes] and multiple runs of non sustained ventricular tachycardia. There is no evidence of significant sustained arrhythmias, and average heart rate ventricular tachycardia is approximately 140-160 beats per minute. During that time the patient was symptomatic, and was mildly lightheaded. Based on our findings, I would recommend that the patient be seen in the outpatient clinic for further antiarrhythmic therapy versus re-attempt at a catheter ablation procedure.

Finally, as reflected in a May 29, 2005 "Medical History & Physical," which was prepared at the time of claimant's heart transplant operation:

> The patient is a 66-year-old male with a long history of end-stage cardiomyopathy secondary to a dilated cardiomyopathy. The patient has been at home with symptoms of heart failure with significant limitation of activity, shortness of breath, and fatigue. He has been hospitalized previously in the past, the last of which in February 2005. The patient has also had previous episodes of nonsustained ventricular tachycardia and atrial fibrillation for which he has had a biventricular pacemaker with AICD placed in June 2004.

Accordingly, claimant has not established a reasonable medical basis for his attesting physician's finding that he suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

We also disagree with claimant that, for purposes of a Level V claim, there is "no difference" between sustained ventricular tachycardia and non-sustained ventricular tachycardia. The Settlement Agreement expressly limits recovery of Level V benefits based on ventricular tachycardia solely to the specific medical condition of sustained ventricular tachycardia. See Settlement Agreement § IV.B.2.c.(5)(d). Accordingly, we decline to rewrite the Settlement Agreement's definition to permit the recovery of Level V benefits for non-sustained ventricular tachycardia. As neither claimant's attesting physician nor his medical records contradict the auditing cardiologist's determination that claimant did not

suffer from sustained ventricular tachycardia, claimant is not entitled to Level V Matrix Benefits under the plain language of the Settlement Agreement.

Finally, we reject claimant's assertion that he is entitled to Level V benefits because all of his heart-related problems are due to the ingestion of Diet Drugs. Causation is not at issue in resolving Mr. Gleave's claim for Matrix Benefits. Rather, Mr. Gleave is required to show that he meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

> ... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97.

The Settlement Agreement unequivocally requires that claimant suffer sustained ventricular tachycardia to receive Level V benefits. We must apply the Settlement Agreement as written. Accordingly, claimant's assertion that his ingestion of

Diet Drugs is the cause of his heart-related problems is not pertinent to the issue before the court.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. Therefore, we will affirm the Trust's denial of Mr. Gleave's claim for Matrix A-1, Level V benefits.